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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,343	04/12/1999	DIRK VOLLENBROICH	2694-119P	9955

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EXAMINER
BRUMBACK, BRENDA G

ART UNIT	PAPER NUMBER
1642	23

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/242,343	VOLLENBROICH ET AL.	
	Examiner	Art Unit	
	Brenda G. Brumback	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-11,13-15,18 and 19*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Brenda Brumback
BRENDA BRUMBACK
PATENT EXAMINER
Primary

Continuation of 5. does NOT place the application in condition for allowance because: while applicant's arguments and the Pauli declaration have been fully considered, they are not persuasive.

Applicant argues that the recited reduction in viral titre is considered to be synonymous with full inactivation of virus. This is not persuasive because while the specification may disclose that in one exemplary preparation the two were synonomous, it does not teach that it is synonomous in each and every case. It is well known in the art that virus preparations may contain more than 100,000 particles and thus inactivation of 100,000 particles in those preparations would not be synonomous with full inactivation of all virus particles.

Applicant argues that the legal standard for inherency has been misapplied in the present case because is is an accidental result and that occasional results are not inherent. It remains the examiner's position that Itokawa et al. anticipates the claimed method because Itokawa et al. performs the same method using concentrations overlapping those of the claimed method. Furthermore, Itokawa performs the method for the same purpose as that claimed, and thus cannot be considered to be an accidental or occasional result.

Applicant's arguments and the Pauli declaration assert that Itokawa et al. and Weislow et al., as well as Naruse et al., do not anticipate the claimed method because all teach reduction in viral infectivity as is measured in cell cultures, which is not equivalent to viral inactivation or direct killing. Itokawa discloses anti-HIV activity as is measured via the cell culture method of Weislow. Naruse teaches antiviral activity as is measured in a cell culture system. The art-recognized standard for measuring viral inactivitation or direct virus killing is to test for viral infectivity in a cell culture system. Testing for viral infectivity in a cell culture system in no way implies or connotes that something other than viral inactivation has occurred. This is unequivocally demonstrated by the attached abstracts and articles, all of which teach testing for viral inactivation using cell cultures.

Applicant's argument that the claimed method is not drawn to a method of administering products in vivo has been previously addressed.

While applicant's assertion that the specification provides support for "cell-free" by disclosing albumin is noted, the disclosure of albumin is not commensurate in scope with the broader recitation of cell free products.